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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,771	04/02/2004	John J. Koleng	BPH-1	2784

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,771	KOLENG ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-26,29-42,44-47,49-54,56 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-26,29-42,44-47,49-54,56 and 57* is/are rejected.

7)☒ Claim(s) *17 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 11/02/2007 are acknowledged.

2. Claims 3, 27-28, 43, 48, 55 and 58 were cancelled.

3. Claims 1, 4, 23, 36, 44, 52 and 56 were amended.

4. Claims 1-2, 4-26, 29-42, 44-47, 49-54, 56-57 are included in the prosecution.

Response to Arguments

Objection to claims 17 and 42

5. Since the objection to claims 17 and 42 for informalities was not addressed by the applicant, the objection will be maintained.

Rejection of claims 1-58 under 35 USC § 103(a)

6. In light of applicant's amendments of claims 1, 23, 36, 44 and 52, to exclude erythritol, the rejection of claims 1-58 under 35 USC § 103(a) as being unpatentable over Murakami et al. (US 6,287,596) in view of Luber et al. (US 2003/0068373), the rejection of 8/7/07 is withdrawn.

7. However, upon further consideration, rejection based on Luber et al. (US 2003/0068373), necessitated by applicant's amendments of claims 1, 23, 36, 44 and 52, follow.

Applicant argues that the '373 Publication of Luber et al. is already described in the Background Section of the instant application. This does not mean that the Luber reference cannot be used as prior art.

Applicant argues that Examiner's description of Luber et al. is not completely accurate and that Luber et al. is directed to a tablet "which is substantially free of water-soluble, non-saccharide polymeric binders" (claim 5) or "which is substantially free of hydrated polymers" (claim 6). This is not persuasive because Luber discloses that other conventional ingredients such as carbohydrates may be included in the tablet (Page 2, [0018]). The prior art reference is not limited to the claims but to the disclosure as a whole.

Applicant states that the instant invention requires one or more hydrophilic polymers, wherein the one or more hydrophilic polymers is a combination of polymers. Applicant states that exemplary polymers of the instant invention, as set forth in the claims include polyethylene glycol, poloxamer, povidone, and co-povidone, so the composition of the invention is not "substantially free of water-soluble, non-saccharide polymeric binders". Luber teaches the hydrophilic polymer, polyethylene glycol (Page 3, [0030]).

Applicant states that all of the instant independent claims (1, 23, 36, 44 and 52) have now been amended to exclude erythritol from the composition. However, this amendment fails to comply with the written description requirement. The amended claims contain subject matter (exclude erythritol from the composition) which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Objections

8. Claims 17 and 42 are objected to because of the following informalities: typo on Page 43, line 21, claim 17, and Page 46, line 13, claim 42, "tamper evident liner" is misspelled "taper evident liner". Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-26, 29-42, 44-47, 49-54, and 56-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 23, 36, 44 and 52 now recite: "... the composition excludes microcrystalline cellulose and erythritol". The amended claims contain subject matter (exclude erythritol from the composition) which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-2, 4-26, 29-42, 44-47, 49-54, 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luber et al. (US 2003/0068373).

The claimed invention is a rapidly dissolving solid oral compressed composition comprising magnesium salt(s) and having a substantially stable dissolution profile after storage for at least two months at 40°C and 75% relative humidity. The composition is prepared by dry granulation or direct compression.

Luber teaches an immediate release tablet comprising an active ingredient and a powdered wax that meets the USP dissolution specification for immediate release tablets containing the active ingredient (Page 1, [0010]). "Most preferably, the active ingredient is selected from the group consisting of ... magnesium hydroxide, magnesium carbonate, magnesium oxide ..." (Page 1, [0011]). It is taught that the "tablet may be designed for swallowing, chewing, or dissolving in the mouth" (Page 2, [0014]). Also disclosed are "conventional dry binders including cellulose, cellulosic derivatives, polyvinyl pyrrolidone, starch, modified starch, ... disintegrants such as ... starch, sodium starch glycolate, crosslinked polyvinylpyrrolidone, ... lubricants, ... glidants, surfactants, ..." (Page 2, [0018]). Direct compression, "dry blending", dry

granulation followed by compression are disclosed as tableting means (Page 2, [0019]). The "degree of particle compaction is controlled so that the resulting tablets have a hardness of about 1 to 30 kiloponds per square centimeter (kp/cm^2)" (Page 2, [0022]). "Optionally, one or more outer coatings may be applied over the tablet to provide protection during packaging and handling" (Page 3, [0025]). Polyethylene glycol is disclosed as a water-soluble polymer (Page 3, [0030]). Examples 1-4 disclose compositions with hardness from 2 - 3.9 kp, and acetaminophen dissolution profiles after storage at 40°C and 75% relative humidity from 1-12 weeks.

The difference between instant claims and Luber is that the composition of Luber contains powdered wax with a melting point greater than about 90°C.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the immediate release tablet containing actives such as magnesium hydroxide, magnesium carbonate, magnesium oxide that meets the USP dissolution specifications, as taught by Luber, and use the powdered wax as an optional lubricant, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because of the excellent tablet disintegration disclosed by Luber (Page 1, [0009]) and the advantage of a stable product when stored at 40°C and 75% relative humidity from 1-12 weeks.

Regarding instant claims 1, 23, 36, 44, and 52, the limitation of the substantially stable dissolution profile according to USP after storage for at least two months at 40°C

and 75% relative humidity would have been obvious to one skilled in the art over the teachings of Luber. Luber teaches immediate release compositions with magnesium salts, hydrophilic polymers and disintegrants. Luber specifically teaches the dissolution profile of actives after 12 weeks at 40°C and 75% relative humidity. One of ordinary skill in the art would find it obvious to make a stable, quickly disintegrating tablet with magnesium salts, store it for 12 weeks at 40°C and 75% relative humidity, and achieve a product with the dissolution profile according to USP for the particular magnesium salt, since Luber discloses stable compositions.

Regarding instant claims 2, 26, 38, and 45, the limitation of the magnesium salts would have been obvious to one skilled in the art over the magnesium antacids taught by Luber.

Regarding instant claims 3, 27, 28, 48, and 55, the limitation of the combination of hydrophilic polymers would have been obvious to one skilled in the art over the water soluble polymers taught by Luber. One with ordinary skill in the art would choose the hydrophilic polymers (or combination of different hydrophilic polymers) depending on the desired release profile.

Regarding instant claims 4, 50, and 56, the limitation of the hydrophilic polymers would have been obvious to one skilled in the art over the Luber disclosure of polyethylene glycol as a water-soluble polymer. Polyvinyl pyrrolidone is disclosed by Luber (Page 2, [0018]).

Regarding instant claims 5, 51, and 57, the limitation of the disintegrant would have been obvious to one skilled in the art over the sodium starch glycolate, and cross linked polyvinyl pyrrolidone teaching of Luber.

Regarding instant claims 6 and 34, the limitation of the coating surrounding the compressed composition would have been obvious to one skilled in the art over the coating of the immediate release tablets of Luber.

Regarding instant claims 7 and 13, the limitation of the tablet or capsule would have been obvious to one skilled in the art over the compressed tablets taught by Luber.

Regarding instant claims 8-9, 19, 29-30, 32-33, 39, 40, 46, and 53, the limitations of dry granulation and direct compression would have been obvious to one skilled in the art over the dry granulation and direct compression taught by Luber.

Regarding instant claims 10, 25, and 37, the limitation of the magnesium salt ranging from being sparingly soluble to being practically insoluble, would have been obvious to one skilled in the art over the magnesium salts taught by Luber which range from being very slightly soluble (magnesium oxide) to being practically insoluble in water (magnesium hydroxide).

Regarding instant claims 11, 24, and 49, the limitation of the magnesium salt present in a therapeutically effective amount would have been obvious to one skilled in the art over the teaching of Luber that magnesium hydroxide, magnesium carbonate, and magnesium oxide can be actives in the tablet.

Regarding instant claims 12 and 35, the limitation of a capsule shell within which the compressed composition is enclosed would have been obvious to one skilled in the art over the coating of the immediate release tablets of Luber.

Regarding instant claim 14, the limitation of tablet hardness would have been obvious to one skilled in the art over the tablet hardness taught by Luber. Luber teaches tablet hardness of 1 to 30 kiloponds per square centimeter (kp/cm^2)" (Page 2, [0022]). Although this range does not exactly match the range of instant claim 14, one skilled in the art would modify the process parameters in order to obtain the desired tablet hardness during the process of routine optimization.

Regarding instant claim 15, the limitation of dissolution medium as dilute hydrochloric acid would have been obvious to one skilled in the art over the dissolution profile at pH 5.8 taught by Luber (Examples 1-4). One skilled in the art would use the USP method of determining the dissolution profile and use the pH buffer specified.

Regarding instant claim 16, the limitation of a sealed container-enclosure system would have been obvious to one skilled in the art because during storage of tablets containing antacids, exposure to moisture would be minimized to prevent degradation of the active antacid material.

Regarding instant claims 17-18, and 42, the limitation of the container-enclosure and sealing system would have been obvious because one skilled in the art would minimize the exposure of the tablets to moisture and choose packaging material in order to do so. The high density polyethylene container, child resistant closures, and

tamper evident liners would have been obvious to one skilled in the art as standard packaging devices used for tablets and solid dosage forms.

Regarding instant claims 20-22, 31, 47 and 54 the limitation of water content ranging from less than 7.5% to less than 4% would have been obvious to one skilled in the art over the dry granulation and direct compression taught by Luber. One skilled in the art would modify the process parameters and levels of components during the process of routine experimentation in order to achieve the desired moisture content in the finished product.

Regarding instant claim 41, the limitation of the process not including the addition of water would have been obvious to one skilled in the art over the dry granulation and direct compression taught by Luber.

Regarding instant claims 43 and 58, the limitation of the composition excluding microcrystalline cellulose would have been obvious to one skilled in the art over examples 1-5 of Luber which exclude microcrystalline cellulose and erythritol.

Conclusion

12. No claims are allowed.

13. The new ground of rejection was necessitated by applicant's amendment.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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